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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,880	10/15/2001	Barry Charles Holdstock	674515-2003 (3038-013)	3435

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EXAMINER	
CHEUNG, WILLIAM K	

ART UNIT	PAPER NUMBER
1796	

MAIL DATE	DELIVERY MODE
02/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/977,880	HOLDSTOCK ET AL.	
	Examiner	Art Unit	
	WILLIAM K. CHEUNG	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9-26,29 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-26,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner acknowledges the receipt of the amendment filed November 17, 2008, claims 7, 8, 27, 28 have been cancelled. Claims 1-6, 9-26, 29, 30 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

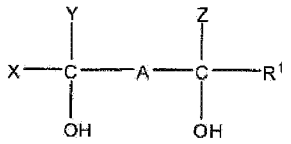
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-6, 9-26, 29, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mancini et al. (US 4,056,496) in view of Mitra et al. (US 5,212,015) as evident in Goto et al. (US 3,845,164), and Williamson et al. (US 6,239,298), further in view of Rohm and Haas, product data sheet on Amberjet product (November 1998), for the reasons adequately set forth from paragraph 6 of the office action of September 19, 2008.

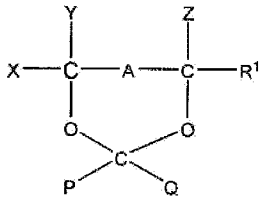
1. (Currently amended). A process for the preparation of a polymerizable composition comprising polymerizable monomer of formula I:



(I)

said process comprising the steps of:

(i) contacting a compound of formula II



(II)

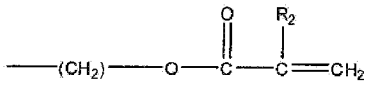
with an immobilized acid to thereby form a composition comprising the monomer of formula (I) and an acid by-product thereof,

wherein

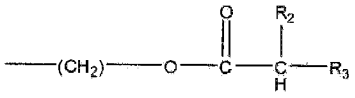
X, Y, Z, P, and Q are independently selected from a hydrocarbyl group or hydrogen,

A is $(CH_2)_n$, wherein n is 0 or 1;

R^1 corresponds to either formula IIIA or formula IIIB



IIIA



IIIB

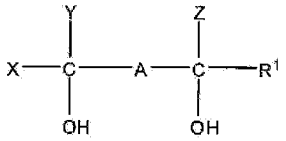
where R_2 is selected from the group consisting of H, methyl, ethyl, propyl, and butyl, and

and

R_3 is an unsaturated C_{2-5} alkyl; and

(ii) neutralizing the composition of step (i) with an immobilized hydroxide, to thereby provide a composition comprising the monomer of formula I and a cross-linker.

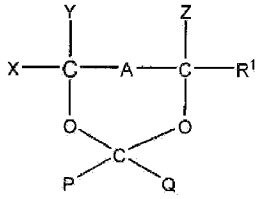
22. (Currently amended) A process for the preparation of a polymerizable composition comprising a polymerizable monomer of formula I:



(I)

said process comprising the steps of:

(i) contacting a compound of formula II



(II)

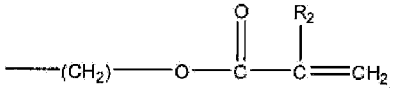
with an immobilized acid, having a pK_a of less than 3 to thereby form a composition comprising the monomer of formula (I) and an acid by-product thereof,

wherein

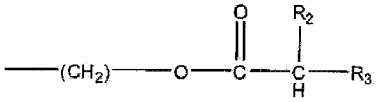
X and Y are independently selected from hydrocarbon groups having 1 to 20 carbon atoms and hydrogen,

Z, P, and Q are independently selected from a hydrocarbyl group or hydrogen, A is $(CH_2)_n$, wherein n is 0 or 1;

R^1 corresponds to either formula IIIA or formula IIIB



IIIA



IIIB

where R_2 is selected from the group consisting of H, methyl, ethyl, propyl, and butyl, and

~~and~~

R_3 is an unsaturated C_{2-5} alkyl; and

(ii) neutralizing the composition of step (i) with an immobilized hydroxide, to thereby provide a composition comprising the monomer of formula I and a cross-linker.

Mancini et al. (col. 3, line 32-48) disclose the deketalization of a compound that is substantially identical to the chemical of Formula II as claimed with a strong acid. Mancini et al. (col. 3, line 50 to col. 4, line 3) in example 1 clearly indicate the use of

concentrated sulfuric acid for the deketalization process, which is also followed by a filtration process.

The difference between the invention of claims 1-6, 9-26, 29, 30 and Mancini et al. is that Mancini et al. are silent on using an immobilized acid for the disclosed deketalization process.

Mitra et al. (col. 18, Example 21) disclose a process to deketalize an organic compound. Since both Mancini et al. and Mitra et al. are both related to the same endeavor of deketalizing organic compounds, it would have been obvious to one of ordinary skill in art to appreciate and combine the deketalization teachings in Mitra et al. and Mancini et al. Further, motivated by the expectation of success of obtaining compounds that are of high purity with Amberlyst-15, which is an immobilized acid (Mitra et al., col. 18, Example 21) comprising sulfonic acid functionalities which are highly acidic by nature, it would have been obvious to one of ordinary skill in art to incorporate the immobilized acid teachings of Mitra et al. into Mancini et al. to obtain the invention of claims 1-6, 9-26, 29, 30.

Regarding the claimed side reaction products, an acrylic acid and a crosslinker, applicants must recognize that deketalized product of Mancini et al. are prompt to side reactions in the presence of a strong acid such as the concentrated sulfuric acid of Mancini et al. or the Amberlyst-15 of Mitra et al. In the presence of a strong acid, the hydrolysis of the deketalized product of Mancini et al. would readily lead to the formation of acrylic acid or methacrylic acid as claimed, which is affirmed by the reference to Goto et al. (col. 4, line 34-37). After reviewing the reference to Goto et al., it would not be

difficult to one of ordinary skill to recognize that the deketalization of Mancini et al. comprises side reaction products, such as acrylic acid or methacrylic acid as claimed.

In view of the reasons set forth above, reaction mixture as disclosed in Mancini et al. clearly disclose a reactive mixture comprising deketalized product of Mancini et al. and acrylic acid or methacrylic acid. In view of the teachings of Williamson et al. (col. 2, line 40-49), it is clearly that the esterification reaction can readily occur between an alcohol (glycerol) and a free carboxylic acid (acrylic acid) in the presence of a strong acid (sulfuric acid) (col. 3, line 9-14). Therefore, after reviewing the reference to Williamson et al. it would not be difficult to one of ordinary skill to recognize the esterification reaction product produced by the reaction of the deketalization of Mancini et al. with the side reaction products, such as acrylic acid or methacrylic acid, to obtain the crosslinker as claimed.

Regarding the claimed "0.50 percent of less of crosslinker" of claim 23, the "essentially quantitative conversion" of claim 25, the "5% or less of a polymer formed by polymerization of said crosslinker" of claim 26, in view of the substantially identical type of reaction as disclosed in the prior art and the reaction type as claimed, the examiner has a reasonable basis that the claimed amount of side reaction product or the "essentially quantitative conversion" are inherently possessed in Mancini et al. and Mitra et al.

The difference between the invention of claims 1-6, 9-26, 29, 30 and Mancini et al. is that Mancini et al. are silent on using an immobilized hydroxide for neutralizing the reaction product.

The Rohm and Haas product literature (page 1, first paragraph) teaches that when an immobilized acid (Amberjet 1500H) is used, it would also be good to use Amberjet 4400 OH to neutralize the medium (reducing the acidity) for regeneration purposes. Motivated by the expectation of success of reducing the acid content in the final product of Mancini et al., it would have been obvious to one of ordinary skill in art to employ the Amberjet 4400 OH teachings (or an immobilized hydroxide) as taught in the Rohm and Haas product literature into Mancini et al. to obtain the immobilized hydroxide feature as claimed.

Applicants must recognize that Mancini et al. (col. 3, line 50-64) clearly express the desire to reduce the acidity of the reaction by washing the reaction product with water. Since water can be considered a base relative to sulfuric acid, and water (H-O-H) possesses a hydroxyl group as well, the examiner has a reasonable basis that the washing step of Mancini et al. can be considered a neutralization step as well.

Applicant's arguments filed November 17, 2008 have been fully considered but they are not persuasive.

Applicants continue to argue that Mitra et al., Goto et al., and Williamson et al. are non-analogous art that can not be used to make up the deficiency on the teachings of Mancini et al. However, the examiner disagrees because the prior art Mitra et al. shares the common endeavors of using dektalized organic compounds with Mancini et al. Regarding Goto et al., and Williamson et al., they are merely references used as evidence for affirming the chemistry rationale set forth for the rejection with Mancini et

al. and Mitra et al. When a reference is used for affirmation purposes, there is no need for a motivational statement.

Applicants argue that Mancini et al. are silent the feature of claim 18 which recites the step of forming the polymer into an ocular device, applicants fail to recognize that Mancini et al. (which is the primary reference for the instant 103 rejection) (col. 1, line 19) clearly teach the composition disclosed is particularly useful for the formation of contact lenses. Therefore, as long as the prior art of Mitra et al. shares the common endeavors of using dektalized organic compounds with Mancini et al., the rejection is proper. Applicants must recognize that the argued common endeavor does not have to be same intended uses in ocular device. The common endeavor can be the deketalization processing steps as taught in Mancini et al. and Mitra et al.

Regarding applicants' argument that the prior art is silent on the feature of claim 29 which claims that prior to neutralizing, the immobilized acid is removed by filtration, applicants must recognize that the rationale set forth by the examiner is adequate since claim 29 does not state which of the components after filtration is being neutralized. Applicants must recognize that Mancini et al. (col. 3, line 50-64) clearly express the desire to reduce the acidity of the reaction by washing the reaction product with water. Since water can be considered a base relative to sulfuric acid, and water (H-O-H) possesses a hydroxyl group as well, the examiner has a reasonable basis that the washing step of Mancini et al. can be considered a neutralization step as well.

Applicants also argue that Rohm and Haas article teaches away from the claimed invention or the invention as taught in Mancini et al. by stating that one should

contact Rohm and Haas for recommendation if a pharmaceutical or medical use is being considered. However, after reviewing the Rohm and Haas article, the article in the Limits of Use section only indicate that one should contact Rohm and Haas for recommendation if a pharmaceutical use is being considered. Since "pharmaceutical" means "drug related", applicants have no basis to include an ocular device as "a drug". Therefore, the examiner has a reasonable basis to believe that the Rohm and Haas article does not teach away from the claimed invention. Further, the teachings of Rohm and Haas article does not teach away from the pharmaceutical application because Rohm and Haas indicate and open invitation of potential customers to contact Rohm and Haas.

American Heritage® Dictionary
phar·ma·ceu·ti·cal
ADJECTIVE:
Of or relating to pharmacy or pharmacists.

Regarding applicants' argument that the Rohm and Haas article only teach the use of Amberjet 4400 OH in a mixed bed application with Amberjet 1500 for industrial uses, and conclude that no neutralization step is taught. Since Mancini et al. do not described any use of a bed of immobilized acid, it would not have been obvious to one of ordinary skill in art to incorporate the mixed bed teachings of Rohm and Haas article. However, the examiner disagrees because Mitra et al. (col. 18, Example 21) clearly disclose a process to deketalize an organic compound. Since both Mancini et al. and Mitra et al. are both related to the same endeavor of deketalizing organic compounds, it would have been obvious to one of ordinary skill in art to appreciate and combine the

deketalization teachings in Mitra et al. Therefore, the examiner has a reasonable basis that the teachings of the Rohm and Haas article can be combined with the teachings of Mitra et al. which clearly disclose the use of Immobilized acid.

Regarding applicants' argument that claim 29 recites that prior to neutralizing, the immobilized acid is removed by filtration and this would be the complete opposite of a mixed-bed operation as taught by the Rohm and Haas article, the examiner is unclear what applicants means by "opposite of a mixed-bed operation".

Regarding applicants' argument that Mancini et al. and Mitra et al. do not teach the side product of the claimed process, applicants must recognize that Mancini et al. (col. 3, line 44) clearly disclose the hydrolysis of dioxolanoalkyl acrylate or methacrylate, which is substantially identical to the chemical structure (II) of claim 1. Therefore, in view of the substantially identical hydrolysis reaction catalyzed by an acid and for the same rationale set forth by applicants relating to the claimed side reaction product of claim 24, the examiner has a reasonable basis that the argued side product of claim 24 is inherently possessed by Mancini et al.

Regarding the newly introduce "immobilized hydroxide" feature, the Rohm and Haas product literature (page 1, first paragraph) teaches that when an immobilized acid (Amberjet 1500H) is used, it would also be good to use Amberjet 4400 OH to neutralize the medium (reducing the acidity) for regeneration purposes. Motivated by the expectation of success of reducing the acid content in the final product of Mancini et al., it would have been obvious to one of ordinary skill in art to employ the Amberjet 4400 OH teachings (or an immobilized hydroxide) as taught in the Rohm and Haas product

literature into Mancini et al. to obtain the immobilized hydroxide feature as claimed. Applicants must recognize that Mancini et al. (col. 3, line 50-64) clearly express the desire to reduce the acidity of the reaction by washing the reaction product with water. Since water can be considered a base relative to sulfuric acid, and water (H-O-H) possesses a hydroxyl group as well, the examiner has a reasonable basis that the washing step of Mancini et al. can be considered a neutralization step as well.

The examiner also notice that most of the arguments are targeted onto the dependents claims, and the arguments are not supported by independent claims 1 and 22, which are related to a process for the preparation of a polymerizable composition. Claims 1 and 22 do not support the argument on pharmaceutical use…etc.

In view of the reasons set forth above, the instant rejection is proper.

Conclusion

4. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William K. Cheung whose telephone number is (571) 272-1097. The examiner can normally be reached on Monday-Friday 9:00AM to 2:00PM; 4:00PM to 8:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David WU can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/William K Cheung/
Primary Examiner, Art Unit 1796

William K. Cheung, Ph. D.
Primary Examiner
February 20, 2009